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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/002,864	11/15/2001	Helga Hoffmann	RDH 2350	4789
321	7590	06/18/2004	EXAMINER	
SENNIGER POWERS LEAVITT AND ROEDEL			GAKH, YELENA G	
ONE METROPOLITAN SQUARE			ART UNIT	PAPER NUMBER
16TH FLOOR			1743	
ST LOUIS, MO 63102			DATE MAILED: 06/18/2004	

Please find below and/or attached an Office communication concerning this application or proceeding.

11

Office Action Summary	Application No.	Applicant(s)
	10/002,864	HOFFMANN ET AL.
Examiner	Art Unit	
Yelena G. Gakh, Ph.D.	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

**A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM
 THE MAILING DATE OF THIS COMMUNICATION.**

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 15 November 2001.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-41 is/are rejected.
- 7) Claim(s) 8 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date: _____
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>03/19/02, 04/24/02</u> .	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
	6) <input type="checkbox"/> Other: _____

DETAILED ACTION

Claim Objections

1. Claim 8 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim 8 recites the substituted imidazole from the group consisting of 1-methyl- (1-Et, 1-Pr, 1-Bu) imidazole, which does not correspond the structural formula for substituted imidazole of the parent claim. In claim 1 R² is selected from the group of Ph, substituted Ph, a fused benzoring and C₁-C₄ substituents, and does not include hydrogen; therefore it cannot be the substituted imidazole recited in claim 8.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. **Claims 1-9, 13, 20, 24-25 and 27-32** are rejected under 35 U.S.C. 102(b) as being anticipated by Scholz (US 5,139,955).

Scholz discloses a Karl-Fischer reagent for determination of water content of a sample, “composed of an alcoholic solvent or solvent mixture in which imidazole and/or an imidazole derivative and/or diethanolamine and/or triethanolamine and sulphur dioxide and an iodide or plurality of iodides and optionally a conducting salt or plurality of conducting salts are dissolved” (Abstract). The imidazole derivative is of the same structural formula as the one recited in claim 1, except for R², which may also be a hydrogen atom. The concentration of imidazole and its derivative is between 0.2 mol/l and 4 mol/l, and for diethanolamine and

triethanolamine between 0.1 mol/l and 2 mol/l, which gives the ratio of the bases between 1:10 and 40:1 (col. 3, lines 36-40); this covers the ranges of ratio recited in claims 29-31. The total amount of bases in the reagent is in the range from 0.3 mol/l to no more than 10 mol/l (2 mol/l + 4 mol/l = 6 mol/l); sulfur dioxide is in the range from 0.05 to 5 mol/l, preferably 0.1 to 2 mol/l (col. 4, lines 50-52). “Examples of suitable alkanols are: **methanol**, ethanol, **propanol**, ethylene glycol, propylene glycol, . . . , benzhydrol and tetraphenylethanol. The alkanols are used individually or, alternatively, mixed with one another. Optionally they are employed mixed with one or more other additional organic solvents, the amount of the alkanol being more than 10, preferably at least 25 per cent by weight of the solvent mixture” (col. 2, lines 28-44). “The reagent according to the invention contains an iodide or a mixture of different iodides. The iodide concentration in the reagent according to the invention is between 0.02 mol/l and 1 mol/l. In the preparation of the reagent, the iodides may be added directly as salts or, alternatively, be prepared by **reacting iodine with water** [which gives hydroiodic acid HI, *Examiner*] in the finally formulated reagent” (col. 3, lines 55-61).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Art Unit: 1743

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. **Claims 10-12, 22-23, 26, 33 and 36-39** are rejected under 35 U.S.C. 103(a) as being unpatentable over Scholz.

Although Scholz does not specifically disclose the ratio of the reagent components as recited in indicated claims, it would have been obvious for anyone of ordinary skill in the art to optimize these ratios to obtain the best results for the reagent, see *In re Aller*, 105 USPQ 233 (CCPA 1955): “the use of optimum amount of a known reactant is within the ambit of one skilled in the art”.

8. **Claims 14-19, 21 and 40** are rejected under 35 U.S.C. 103(a) as being unpatentable over Scholz in view of Fischer et al. (US 4,851,352).

Scholz does not specifically disclose ethylene or diethylene glycol monoalkylethers as the alcohol solvents.

Fischer discloses Karl Fischer reagent containing alcohol solvents, comprising ethylene glycol monoalkyl ethers: “suitable ethylene glycol monoalkyl ethers are preferably those having an alkyl group containing 1-8 carbon atoms, particularly ethylene glycol monomethyl and monoethyl ether. Corresponding derivatives of the diethylene and triethylene glycol monoalkyl ethers are also suitable, for example, diethylene glycol monomethyl ether, etc.” (col. 2, lines 17-24).

It would have been obvious for anyone of ordinary skill in the art to change alcohol solvent proposed for Karl Fischer reagent by Scholz with the alcohol solvent of Fischer, because Fischer expands Scholz’s list of suitable alcohol solvents by including various ethylene glycol monoalkyl ethers.

9. **Claims 34-35** are rejected under 35 U.S.C. 103(a) as being unpatentable over Scholz in view of Sherman et al. (Accreditation and Quality Assurance, May 1999).

While Scholz does not specifically indicate the optimal pH range for his Karl Fischer reagent, Sherman indicates “pH of the KF [Karl Fischer] reagent (i.e., pH 5.5–8 with such bases as pyridine or imidazole” [Google search with highlighted keywords, text excerpt from the article].

It would have been obvious for anyone of ordinary skill in the art to adjust pH of KF reagent disclosed by Scholz to 5.5-8 with such bases as pyridine or imidazole, because this is the optimal pH range for this reagent, as indicated by Sherman.

10. **Claim 41** is rejected under 35 U.S.C. 103(a) as being unpatentable over Scholz in view of Fischer as applied to claims 14-19, 21 and 40 above, and further in view of Sherman.

While Scholz in view of Fischer do not specifically indicate the optimal pH range for his Karl Fischer reagent, Sherman indicates “pH of the KF [Karl Fischer] reagent (i.e., pH 5.5–8 with such bases as pyridine or imidazole” [Google search with highlighted keywords, text excerpt from the article].

It would have been obvious for anyone of ordinary skill in the art to adjust pH of KF reagent disclosed by Scholz in view of Fischer to 5.5-8 with such bases as pyridine or imidazole, because this is the optimal pH range for this reagent, as indicated by Sherman.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yelena G. Gakh, Ph.D. whose telephone number is (571) 272-1257. The examiner can normally be reached on 9:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Yelena G. Gakh
6/15/04

Yelena Gakh